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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/486,703	06/27/2000	IAN ROSS DOYLE	13704/2	9876

26646 7590 07/18/2007

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EXAMINER	
DUFFY, PATRICIA ANN	
ART UNIT	**PAPER NUMBER**
1645	

MAIL DATE	DELIVERY MODE
07/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 09/486,703	**Applicant(s)** DOYLE ET AL.	
	Examiner Patricia A. Duffy	**Art Unit** 1645	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 07 June 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
   b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *51-64*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☒ Other: 892.

Patricia A. Duffy
Primary Examiner
Art Unit: 1645

Continuation of 11. does NOT place the application in condition for allowance because: Applicants arguments have been carefully considered. Applicants argue that the patient populations of Doyle et al do not necessarily encompass the patient populations of "asymtopmatic to lung damage" or "wherein the clinical diagnosis of lung damage in a mammal cannot be otherwize confirmed without the aid of one or more invasive proceedures". Applicants argue that normal indivuduals or the OND patient population do not necessarily encompass either of the claimed patient populations. This is not persuasive because the terms are given their broadest reasonable interpretation. "Asymptomatic" is defined in the art as "without obvious signs or symptoms of disease" (Online Medical Dictionary) or "without symptoms, or producing no symptoms" (Stedman's Medical dictionary 27th edition). "Normal" is defined by the art to be "not diseased". As such the "normals" as not diseased are necessarily asymptomatic of lung damage because they do not by any definition have lung disease. The specifiction does not narrowly construe the population of "asymptomatic individuals" as argued as patients as healthy indivuduals. The "higher degree of inquiry" associated with "asymptomatic" is necessarily included in "normals" and "OND" because one had to ascertain that they did not have lung disease. The specifiction does not define the population as having a higher degree of inquiry and the higher degree of inquiry is not set forth in the specificaiton. The assertion that "normal" is simply not diagnosed with disease is inconsistent with the art accepted definition of the term in the medical dictionary (see Stedman's Medication Dictionary 27th Edition). Further, there is no requirement that the "asymptomatic patients" or "normal" patients have lung damage, because it is merely screening for an increase. Doyle et al teach the criteria for inclusion.. no history or nor history and current evidence as such, the populations of Doyle et al meet the criteria of "higher inquiry". Further, there is no evidence in Doyle et al that the normal indivulals tested, with no history of disease, did in fact have disease (see page 1222, column 1, first full paragraph). One skilled in the art given the test results described in Doyle et al demonstrating that the normals were without disease would indicate that these individuals were necessarily asymptomatic for lung disease. Applicants argue "normal" contrary to the accepted definition in the art as "not diseased". The data support the examiners position that the normal group was in fact normal according to the art standards and that normal individuals do not display the signs or symptoms of the disease that they are free from. In contrast to the citation of judicial precident argued by Applicants, the data presented in Doyle et al demonstrating that none of the pateints classified as "normal" or "OND" would necessarily meet the claimed patient population. Patients without disease are necessarily asymptomatic or cannot be diagnosed without invasive proceedures specific to that disease, because they do not have disease. The single step is met by the prior art populations because the claims do not require that the screened patient have an increase because the test could be negative. Applicants argue a standard of criteria that is not set forth in the specification as filed. Applicants argue the 103 over Doyle et al, since Doyle et al does not fail, neither does the combination over it. .